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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Randolf von Oepen

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08/12/2010

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EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

08/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/015,274	Applicant(s) VON OEPEN, RANDOLF	
	Examiner Brian-Yong S. Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16 and 18-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14, 16 and 19-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner for the instant application has changed. The current examiner assigned to this application is Brian-Yong S. Kwon. Claims 14, 16 and 19-34 are presented for examination.
2. Acknowledgement is made of applicant's amendment/remarks filed on 02/02/2010. By the amendment claims 14, 19, 30-34 have been amended and claim 34 has been cancelled.
3. Upon further consideration of the claimed invention, the examiner requires further election/restrictions as followings.

Election/Restrictions

4. This application contains claims directed to the following patentably distinct species: (i) a first member of the specific binding pair selected from protein, nucleic acid, carbohydrate, lipid, RNA, DNA, antibody, antigen, epitope, lectin, receptor, ligand, avidin, streptavidin, biotin, heparin or protamine, (ii) a second member of the specific bind pair selected from protein, nucleic acid, carbohydrate, lipid, RNA, DNA, antibody, antigen, epitope, lectin, receptor, ligand, avidin, streptavidin, biotin, heparin or protamine and (iii) radioactive moiety selected from "yttrium-90, iodine-125, iodine-132....". The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of above (i) a first member, (ii) the second member and (iii) radioactive moiety , for example epitope from a first member, antibody from a second member and iodine-131, for prosecution on

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the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. In addition, applicant is required under 35 U.S.C. 121 to elect a single disclosed species under the instant claims of the elected Group II as followings:

II(a). A kit comprising (a) an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of radioactive moiety and/or a neutron-capture moiety to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being bound to a second member of the specific binding pair, wherein the second member of the specific binding pair being capable of binding to the first member (described in claims 14, 16, 19, 21-32 and 34).

II(b). A kit comprising (a) an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of radioactive moiety and/or a neutron-capture moiety to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being bound to a second member of the specific binding pair, wherein the second

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member of the specific binding pair being capable of binding to the first member, and (c) an agent for selectively disrupting the specific binding pair (described in claim 20).

II(c). A kit comprising (a) an intravascular medical device having a surface and more than one species of first members of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of more than one species of radioactive moieties and/or a neutron-capture moieties to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being bound to more than one species of second members of the specific binding pair, wherein the second members of the specific binding pair being capable of binding to the first members (described in claim 34).

6. Furthermore, applicant is required under 35 USC 121 to elect a single disclosed species from the elected Group II as followings:

II(c) A kit comprising (a) an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of radioactive moiety and/or a neutron-capture moiety to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being bound to a second member of the specific binding pair, wherein the second

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member of the specific binding pair being capable of binding to the first member, and wherein the first member or the second member is bound to the surface via chemical functional group (described in claim 26), for example carboxylate group.

- II(d). A kit comprising (a) an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of radioactive moiety and/or a neutron-capture moiety to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being bound to a second member of the specific binding pair, wherein the second member of the specific binding pair being capable of binding to the first member, and wherein the first member or the second member is bound to the surface via linker moiety, for example protein (described in claim 25).

7. Furthermore, applicant is required under 35 USC 121 to elect a single disclosed species from the elected Group II as followings.

- II(e) A kit comprising (a) an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of radioactive moiety and/or a neutron-capture moiety to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being bound to a second member of the specific binding pair, wherein the second

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member of the specific binding pair being capable of binding to the first member, wherein the first member or the second member is bound to the surface via chemical functional group and wherein the second member is connected to a radioactive moiety via a molecular linker (described in claim 30).

- II(f). A kit comprising (a) an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of radioactive moiety and/or a neutron-capture moiety to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being bound to a second member of the specific binding pair, wherein the second member of the specific binding pair being capable of binding to the first member, wherein the first member or the second member is bound to the surface via chemical functional group and wherein the second member is connected to a radioactive moiety via a chelating group (described in claim 31).

8. Furthermore, applicant is required under 35 USC 121 to elect a single disclosed species from the elected Group II following.

- II(g) A kit comprising (a) an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of radioactive moiety and/or a neutron-capture moiety to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being

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bound to a second member of the specific binding pair, wherein the second member of the specific binding pair being capable of binding to the first member, wherein the first member is immobilized to a coating covering of the surface (described in claim 21).

- II(h) A kit comprising (a) an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface and (b) a perfusion catheter configured for delivery of radioactive moiety and/or a neutron-capture moiety to the intravascular medical device after implantation at an implantation site, wherein the radioactive moiety or the neutron-capture moiety each being bound to a second member of the specific binding pair, wherein the second member of the specific binding pair being capable of binding to the first member, wherein the first member is immobilized to an expandable film lining of the surface (described in claim 22).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as

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an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614